

# CMS SOLICITING COMMENTS ON OFFICE-BASED CATARACT SURGERY

The Centers for Medicare & Medicaid Services (CMS) is seeking public comment regarding the advisability of paying for cataract surgery in the office-based surgical suite. Whereas CMS cites potential advantages of performing cataract surgery—the highest-volume procedure performed on Medicare beneficiaries—in an office setting, several stakeholders have raised concerns regarding patients' safety and compliance.

In a small section of its 815-page proposed 2016 Medicare fee schedule regulation,<sup>1</sup> CMS cites a number of perceived advantages to implementing an office-based policy, including advances in technology, convenience for patients, flexibility in scheduling surgery, and lower Medicare expenditures.

"Advancements in technology have significantly reduced operating time and improved both the safety of the procedure and patient outcomes," a portion of the CMS Medicare fee schedule read. "We believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. Cataract surgery patients require a sterile surgical suite with certain equipment and supplies that we believe could be a part of a nonfacility-based setting that is properly constructed and maintained for appropriate infection prevention and control."

Experts with an interest in keeping procedures in an ambulatory surgical center (ASC) setting, however, have raised concerns.

"While fair and equitable reimbursement of ASCs is always a concern (lest facilities will be unable to offer high-quality, affordable, and accessible eye surgery), we view patient health and safety as our first priority," Michael A. Romansky, JD, vice president of corporate development and Washington counsel for the advocacy group Outpatient Ophthalmic Surgery Society (OOSS), said in a statement to *CRST*. "The growth in volume of cataract surgery and our exceptional outcomes and very low incidence of TASS [toxic anterior segment syndrome] and other complications are testaments to this 'patient first' commitment. OOSS supports reasonable regulation

of ASCs, and our centers meet and commonly exceed requirements established by Medicare, state health regulatory bodies, and facility accreditation agencies."

Dr. Romansky said it is critical that patients' health and safety be considered before any incentives are provided for office-based surgery.

"We believe that CMS's request for information regarding appropriate payment for office surgery puts the cart before the horse," he said. "Before providing incentives for surgeons to perform cataract surgery in their offices, the agency should work with the ophthalmology and ASC communities to examine whether surgery can be safely performed in the office setting, what specific patient health and safety standards should be applied, and what form of oversight is required."

Robert Weinstock, MD, director of cataract and refractive surgery, Eye Institute of West Florida, Largo, Florida, and chief medical editor of *CRST*, said CMS's solicitation for feedback is an opportunity for surgeons to voice their opinions on the viability of office-based cataract surgery.

"It's clearly our responsibility to approach this subject from a patient-centric perspective," Dr. Weinstock said in a statement to *CRST*. "Not long ago, cataract surgery was done in the hospital with a 3- to 7-day inpatient stay, and implants were considered experimental. We all know how quickly things have changed, and it would not surprise me if things continue to evolve. Regardless of the direction this goes, it's important for ophthalmologists to stay involved and help foster a viable model for a continued improvement in safety and visual outcomes for our patients."

Comments may be submitted to CMS until September 8, 2015, either electronically at [www.regulations.gov](http://www.regulations.gov) or through the mail at Centers for Medicare & Medicaid Services, Department of Health and Human Services, CMS 1612-P2, Attention: CMS-1631-P; P. O. Box 8013, Baltimore, MD 21244-8013.

1. Centers for Medicare & Medicaid Services (CMS), HHS. Medicare program; revisions to payment policies under the physician fee schedule and other revisions to part B for CY 2016. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16875.pdf>. Pages 53-55. Published online July 15, 2015. Accessed July 20, 2015.

## The Victus Receives Clearance for Enhanced Patient Interface Kit

The Victus Femtosecond Laser Platform (Bausch + Lomb) has received 510(k) clearance from the FDA for an enhanced patient interface kit, according to a news release. The interface features a smaller-diameter suction clip. The modification reportedly allows easier opening and closing of the clip to help facilitate more efficient placement in patients with narrow fissures and smaller eye openings.

Additional features of the enhanced patient interface kit, which is intended to improve the performance of the suction ring as well as laser operation function, include a colored skirt on the suction clip to assist surgeons in achieving optimal centration to avoid tilt and optimize the inner working diameter of the suction ring. Multiple suction ports along the inside of the ring were incorporated to assist surgeons in obtaining optimal control of the eye throughout the Victus Femtosecond laser procedure. Also, an enhanced contoured handle give surgeons a comfortable grip and improved control of the suction clip, including an easy lock/unlock feature.

Earlier this year, the Victus received 510(k) clearance from the FDA for an advanced swept source optical coherence tomography imaging system and updated software that allows customized treatment planning for improved efficiency and patient flow during surgical procedures. The platform has additional CE Marks, including corneal incisions, penetrating keratoplasty, and the creation of intrastromal channel incisions for intracorneal ring segments.

## Shire Acquires Foresight Biotherapeutics

Shire has acquired privately held Foresight Biotherapeutics for \$300 million, according to a news release. With the acquisition, Shire gains the global rights to FST-100 (topical

ophthalmic drops combining 0.6% povidone-iodine and 0.1% dexamethasone), a therapy in late-stage development for the treatment of infectious conjunctivitis. Shire will evaluate an appropriate regulatory filing strategy for additional markets outside the United States. If approved by regulatory agencies, FST-100 has the potential to become the first agent to treat both viral and bacterial conjunctivitis, the company said.

The phase 2 proof-of-concept efficacy and safety clinical trial program for FST-100 involved two studies in adenoviral conjunctivitis—one three-armed study and another two-armed pilot study. Although the two-armed study showed a trend toward efficacy, there were too few subjects testing positive for a viral presence for the study to deliver meaningful results, and the results were not statistically significant.

In the three-armed study, patients were randomized to receive FST-100, 0.6% povidone-iodine, or vehicle four times daily for 5 days. According to the company, patients treated with FST-100 showed a statistically significant improvement in rates of clinical cure and viral eradication versus vehicle at day 6 (30.6% vs 6.4%,  $P = .0033$ ). In the same trial, there was a trend toward clinical significance for FST-100 versus 0.6% povidone-iodine (30.6% vs 18.0%,  $P = .1432$ ). The most common treatment emergent adverse events were corneal infiltrates (19%), punctate keratitis (22.4%), and eyelid edema (12.1%).

The phase 2 clinical data formed the basis of a meeting with the FDA, in which Foresight Biotherapeutics discussed the path forward to conduct a phase 3 clinical development program for FST-100 as a potential treatment for adenoviral conjunctivitis. Upon close of the transaction, Shire will take responsibility for the final development and implementation for the phase 3 clinical program for FST-100, which will also include investigation for the treatment of bacterial conjunctivitis. Foresight Biotherapeutics conducted pre-clinical experiments evaluating the bacterial killing speed of FST-100 against pathogens that may cause bacterial conjunctivitis, and the resulting data reportedly support further exploration.

## PEARLS FROM THE DEEP

By Cynthia Matossian, MD

Having a successful business requires more than just hard work. You also have to master the art of working “smart.” One way to do this is to protect yourself from inflated credit card processing rates and eliminate hidden fees that are buried in your statements.

Merchant Advocate is recognized as an expert in the credit card processing industry and has a consistent record of advocacy on behalf of you, the merchant. The services provided include

- **Analysis.** The team at Merchant Advocate provides a free analysis of your credit card statement.
- **Adjustments.** They negotiate with your current

processor to lower rates and eliminate hidden fees.

- **Audits.** The Merchant Advocate staff monitors your account every month to ensure the processor does not increase rates or slip in hidden fees.

Your business does not need to switch credit card processors or interrupt long-standing banking relationships. Moreover, there are no upfront costs for the Merchant Advocate services; they are paid out of the savings they achieve for you, recovering revenue that would otherwise be lost. They pride themselves on their transparency as they help you look for buried credit card fees and penalties. For example, the processor (ie, the merchant account provider) can

introduce fees upwards of \$30 per month if you do not complete their payment card industry survey.

For more information, visit <http://advocate.com>. We at Matossian Eye Associates have been using Merchant Advocate for several years with great success.

*To learn more about and register for the 2016 ACES/SEE Caribbean Eye meeting, visit [www.caribbeaneyemeeting.com](http://www.caribbeaneyemeeting.com).*

*Cynthia Matossian, MD, is the founder and CEO of Matossian Eye Associates. She acknowledged no financial interest in Merchant Advocate. Dr. Matossian may be reached at [cmatossian@matossianeye.com](mailto:cmatossian@matossianeye.com).*

## Allergan Sells Its Global Generics Business to Teva for \$40.5 Billion

Teva Pharmaceutical announced that it has signed a definitive agreement with Allergan to acquire Allergan's generics business in a transaction valued at \$40.5 billion, according to a company news release. Upon closing, Allergan will receive \$33.75 billion in cash and shares of Teva valued at \$6.75 billion, representing an estimated under 10% ownership stake in Teva, with the number of Teva shares determined based on Teva's volume-weighted average trading prices during the 15 days prior to the announcement and 5 days following the announcement. Teva believes the acquisition will be significantly accretive to nongenerally accepted accounting principles earnings per share, including expected double-digit nongenerally accepted accounting principles earnings per share accretion in 2016 and more than 20% accretion in year 2 and year 3 following the close of the transaction. The transaction was unanimously approved by the boards of directors of Teva and Allergan and is expected to close in the first quarter of 2016. ■



## LETTERS

### TRUTH AND MYTH

*The following letter regards an editorial by Steven J. Dell, MD, "Oscar Zoroaster Phadrig Isaac Norman Henkle Emmannuel Ambroise Diggs," which appeared in our May 2015 edition.*

Dr. Dell's editorial is exceptional. Its essence is the power of myth. In his 1962 commencement address at Yale University, President John F. Kennedy stated, "For the great enemy of the truth is very often not the lie—deliberate, contrived, and dishonest—but the myth—persistent, persuasive, and unrealistic."<sup>1</sup> People like Dr. Oz (or even Oprah Winfrey) prey on myth. People are gullible. In 1991, Joseph Campbell wrote an extraordinary book by the title of *The Power of Myth*.

My mentor in London used to say, "There are three solutions for every problem or any problem. First is education, second is education, and the third is education." Are we able to educate our trusting and ignorant public? ■

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1. Kennedy JF. Commencement address at Yale University. The American Presidency Project website. June 11, 1962. <http://www.presidency.ucsb.edu/ws/?pid=29661>. Accessed July 30, 2015.